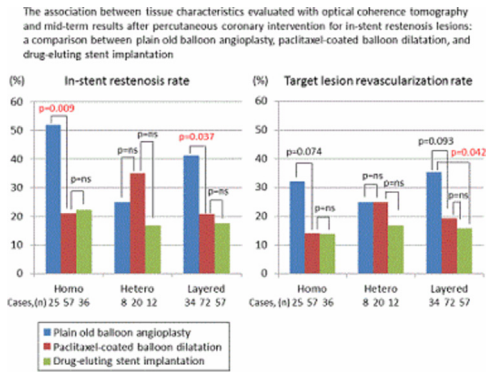
old balloon angioplasty (POBA), paclitaxel-coated balloon dilatation (PCB), and drug-eluting stent (DES) implantation.
Methods: Between July 2008 and May 2012, we performed PCI for 321 ISR lesions using POBA (67 lesions, POBA group), PCB (149 lesions, PCB group), and DES (105 lesions, DES group). The morphological assessment of neointimal tissue at the minimum lumen area site as to restenotic tissue structure (homogeneous, heterogeneous, or layered type) using OCT was performed. We examined the association between tissue structure and mid-term (6-8 months) results including ISR and target lesion revascularization (TLR) rates.
Results: The patients were 263 men and 58 women, and the mean age was 68.9±9.6 years. The mean follow-up period was 209±38 days. The association of tissue structure with ISR and TLR rates in each groups is shown in the figure. The ISR rates of lesions with homogeneous and layered structure were significantly lower in the PCB and DES groups than in the POBA group, whereas there were no differences between 3 groups in heterogeneous structure.



Conclusions: The morphological assessment of ISR tissue using OCT might suggest favorable types of PCI for ISR lesions.

TCT-72

PCI Lesion Morphology According to Chronic Statin Use: An ADAPT-DES IVUS Substudy

Cristiano F. Souza[1], Gary S. Mintz[2], Bernhard Witzenbichler[3], D. Christopher Metzger[4], Michael Rinaldi[5], Ernest L. Mazzaferri[6], Peter L. Duffy[7], Giora Weisz[8], Thomas Stuckey[9], Bruce R. Brodie[10], Ke Xu[1], Gregg W. Stone[11], Akiko Maehara[12]
[1]Cardiovascular Research Foundation, New York, NY, [2]Cardiovascular Research Foundation, washington, DC, [3]Charité Campus Benjamin Franklin, Berlin, Germany, [4]Wellmont CVA Heart Institute, Kingsport, TN, [5]Associate Professor of Medicine, UNC Chapel Hill, Charlotte, NC, [6]Ohio State University, Dublin, OH, [7]Pinehurst Cardiology, Pinehurst, NC, [8]Columbia University, New York, United States, [9]Lebauer Cardiovascular Research Foundation, Greensboro, NC, [10]LeBauer CV Research Foundation, Greensboro, NC, [11]Cardiovascular Research Foundation, NY, NY, [12]Cardiovascular Reserach Foundation and Columbia University Medical Center, New York, United States

Background: Previous IVUS studies, due to small size, were not able to establish a relation between statin use and its impact on plaque composition by grayscale and VH-IVUS.
Methods: ADAPT-DES was a prospective multicenter study of 8,583 pts undergoing percutaneous coronary intervention (PCI) using drug-eluting stents. A pre-specified grayscale and VH-IVUS sub-study enrolled 2,064 pts. Pre-PCI imaging of 773 pts identified 907 culprit lesions. Pts with vs without statin use prior to hospital admission were compared.
Results: Overall, 43.6% (377) of pts were treated with statins prior to admission. Pts using statins were older and had a higher prevalence of risk factors such as diabetes (33% vs 20%, p<0.0001), hypertension (90% vs 59%, p=0.02), and renal insufficiency (creatinine clearance <60 ml/min, 14% vs 7%, p=0.001). At admission, statin pts were frequently taking medications such as aspirin, ACEI/ARB, and beta-blockers (all p<0.0001). Statin pts were more likely to present with more stable angina, while non-statin pts more frequently presented with ST-segment elevation (STE) and non-STE acute coronary syndromes (Table). Statin pts were more likely to have angiographic 3-vessel disease and calcification. Grayscale and VH-IVUS findings showed that statin pts had slightly larger minimum lumen area (MLA) along with less plaque burden, but with more dense calcium (DC). Statin pts had more calcified thick-cap fibroatheromas (ThCFA: necrotic core >10%, confluent DC >10%, well-defined fibrous cap), but fewer thin-cap fibroatheromas (TCFAs) or plaque ruptures.

	Statin use (n=337)	No statin (n=436)	p-value
ACS presentation	37.7% (127)	69.7% (304)	<0.0001
Angiographic findings			
Three vessel disease	33.5% (113)	21.6% (94)	0.0002
Any calcification	46.6% (157)	38.5% (168)	0.02
IVUS findings			
Minimum lumen area (MLA), mm^2	3.1 [2.9, 3.2]	2.7 [2.6, 2.8]	<0.0001
Plaque volume, %	56.1 [55.2, 57.1]	58.1 [57.3, 58.9]	0.003
Dense calcium volume, %	11.8 [11.0, 12.7]	9.5 [8.9, 10.1]	<0.0001
Plaque rupture	26.6 % (107)	38.4% (197)	0.0002
TCFA at MLA site	10.7% (43)	14.2% (73)	0.12
Any lesion TCFA	45.2% (182)	56.1% (288)	0.001
Calcified-ThCFA at MLA site	24.6% (99)	15.8% (81)	0.0008

Conclusions: Chronic statin use in PCI patients was associated with more stable clinical presentation and IVUS findings consistent with greater lesion stability (fewer VH-TCFAs and plaque ruptures, more ThCFAs) compared to pts with CAD who were not taking statins.

TCT-73

Forward-Looking IVUS: Technology Overview and First-in-human Case Review

Carlos I. Mena[1], Dierk Scheinert[2]
[1]Yale School of Medicine, New Haven, CT, [2]Park-Krankenhaus Leipzig, Leipzig, Germany

Background: Chronic total occlusions of the vessels in the periphery are often encountered and present significant technical challenges. The presence of occlusive disease is associated with higher rates of failed re-canalization and worse long term results. Currently, subintimal dissection and re-entry techniques are commonly used to treat these challenging lesions. For all subsequent therapy, including angioplasty, stenting and atherectomy, the ability to cross occlusions while staying within the true lumen is preferred. Devices and techniques which allow re-canalization through the true lumen represent an important and unmet clinical need. Forward-looking IVUS (FL.IVUS) is a new technology that has been developed to provide real-time therapy guidance while crossing challenging peripheral occlusions.
Methods: A non-randomized, non-blinded, multi-center, first-in-man, four-phase, prospective study was performed to assess the safety and feasibility of the Forward-looking IVUS system in subjects with peripheral artery disease undergoing endovascular therapy. In the fourth phase of this study, the FL.IVUS device was used to provide real-time guidance while crossing CTOs in iliac and femoral vessels.
Results: Twenty cases were completed at three centers to assess the safety and feasibility of the Forward-looking IVUS system in crossing peripheral chronic total occlusions. The FL.IVUS catheter provided real-time images of the vessel and occlusion. These images were used for guidewire placement and to confirm true lumen position while crossing the CTOs. Two cases from the first-in-human series will be presented to highlight the clinical utility and imaging performance of the FL.IVUS system.
Conclusions: A novel Forward-looking IVUS device was used to provide real-time, intraluminal guidance for the treatment of CTOs in the iliac and femoral arteries. This first-in-human clinical series demonstrates the preliminary safety and feasibility of this novel imaging modality for the endovascular treatment of complex peripheral artery disease. Future directions for the technology include improved catheter performance and new imaging and software features.